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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,383	06/13/2007	Cathy Lofton-Day	47675-065US0	3836
22504 7590 04/13/2010 DAVIS WRIGHT TREMAINE, LLP/Seattle 1201 Third Avenue, Suite 2200 SEATTLE, WA 98101-3045				
EXAMINER				
LU, FRANK WEI MIN				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
04/13/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/562,383

**Applicant(s)**

LOFTON-DAY ET AL.

**Examiner**

FRANK W. LU

**Art Unit**

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/7/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-43, 45-51, 53, 55 and 57-59 is/are pending in the application.
- 4a) Of the above claim(s) 46-51, 53, 55 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8, 10-43 and 45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 1-45 and ALX-4 (SEQ ID NO:5) in the reply filed on January 7, 2010 is acknowledged. The traversal is on the ground(s) that "[T]he basis of Applicants' traversal is that the elected claims should also be examined with respect to the related bisulfite-converted sequences of SEQ ID NO:5; namely SEQ ID NOS:312, 313,428, and 429, based on the fact that they represent the same genomic sequence. Specifically, SEQ ID NOS: 312, 313,428 and 429 correspond to chemically-treated (bisulfate) versions of SEQ ID NO:5, wherein SEQ ID NOS: 312 (sense) and 313 (antisense) correspond to treated sequences wherein the CpG dinucleotides of SEQ ID NO:5 are methylated, and wherein SEQ ID NOS:428 (sense) and 429 (antisense) correspond to treated sequences wherein the CpG dinucleotides of SEQ ID NO:5 are unmethylated. **The elected claims should, therefore, not only be examined with respect to SEQ ID NO:5, but additionally with respect to each of SEQ ID NOS: 312, 313, 428, and 429,** because they correspond to bisulfite-treated sequences for the identical sequence region of genomic SEQ ID NO:5 and the patentability of claims limited by these SEQ ID NOS will be determined based on the novelty of analysis based on this genomic sequence region for the claimed indications. Finally, in the event that a specific ALX 4 oligo, primer and/or probe ,*species* election is subsequently required for the ALX 4 gene are as follows, and should be included with respect to examination of any claims reciting a ALX 4 gene primer and/or probe, if needed: Oligonucleotides: SEQ ID NOS: 697-716. Left Primer: SEQ ID NOS:3028,3032,3033,3036,3037,3038,3039,3041,3042,3043,3044,3047,3048,3049,3052,3055, 3059,3061,3064,3065,3068,3069,3071,3072,3075,3076,3080,3083,3084,3085,3086,3091,3093,

3096,3097,3100,3104,3109,3110,3113,3115,3117,3118,3123,3126,3127,3130,3134,3135,3136, 3138,3139,3144,3146,3147,3149,3150,3155; Right Primer: SEQ ID NOS: 3029,3031,3034,3040, 3045,3050,3051,3053,3054, 3056,3057,3060,3063,3066,3073,3078,3081,3088,3089,3090,3092, 3094,3098,3101, 3103,3105,3107,3108,3111,3114,3116,3119,3121,3122,3124,3128,3131, 3133, 3137, 3140,3142,3145,3148,3151,3152,3153,3157;and Detection Probes: SEQ ID NOS: 3030, 3035,3046,3058,3062,3067,3070,3074,3077, 3079,3082,3087,3095,3099,3102,3106,3112,3120, 3125,3129,3132,3141,3143,3154, 3156,3158. In summary, the elected claims should be examined at least with respect to each of SEQ ID NOS:5, 312, 313, 428 and 429. Applicants point out that it has been the consistent practice of the Office to include the bisulfite-treated sequences with the underlying genomic sequence for examination. Furthermore, Applicants request that the above-identified ALX 4 oligo, primer and probe sequences be included as discussed above, if species elections are subsequently required”.

After carefully considering applicant’s arguments, the examiner agree to examine SEQ ID NOS:5, 312, 313, 428 and 429, all Left Primers including SEQ ID NOS:3028,3032, 3033, 3036,3037,3038,3039,3041,3042,3043,3044,3047,3048,3049,3052,3055, 3059, 3061,3064, 3065, 3068,3069,3071,3072,3075,3076,3080,3083,3084,3085,3086,3091,3093, 3096, 3097, 3100, 3104,3109,3110,3113,3115,3117,3118,3123,3126,3127,3130,3134,3135,3136,3138,3139, 3144, 3146,3147,3149,3150, and 3155, all Right Primers including SEQ ID NOS: 3029,3031, 3034, 3040, 3045, 3050,3051,3053,3054, 3056,3057,3060, 3063,3066,3073,3078, 3081, 3088, 3089, 3090,3092, 3094,3098,3101, 3103,3105,3107,3108,3111,3114,3116,3119, 3121,3122, 3124, 3128,3131,3133, 3137, 3140,3142,3145,3148,3151,3152,3153, and 3157, and all Detection Probes: SEQ ID NOS:3030,3035,3046,3058,3062,3067,3070,3074,3077,3079, 3082,3087,

3095,3099, 3102, 3106, 3112,3120,3125,3129,3132,3141,3143,3154, 3156, and 3158. However, in view of claims 1-8, 10-43, and 45 (claims 9 and 44 have been canceled by applicant), the examiner cannot locate claims 697-716. Thus the examiner considers that claims 697-716 are not elected by applicant. Since applicant has not argue to combine Groups I and II, the requirement on Groups I and II is still deemed proper and is therefore made FINAL.

### *Election of Species*

2. In view of elected claims 1-8, 10-43, and 45, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (1) said expression level is determined by detecting the presence, absence or level of mRNA transcribed from said gene or sequence (claim 4)
- (2) said expression level is determined by detecting the presence, absence or level of a polypeptide encoded by said gene or sequence (claims 5 and 6)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the

limitations of an allowed generic claim. Currently, the following claim(s) are generic: claims 1-3, 7, 8, 10-43, and 45.

#### REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

#### WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /  
Primary Examiner, Art Unit 1634  
April 9, 2010